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SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER EVANISKO, GEORGE ROBERT	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/650,207
Filing Date: August 28, 2003
Appellant(s): JANKE ET AL.

Peter C. Maki
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/30/07 appealing from the Office action mailed 8/4/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,886,074	Bisping	12-1989
4,624,265	Grassi	11-1986
5,217,028	Dutcher et al	6-1993

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4,819,661	Heil, Jr. et al.	4-1989
5,871,531	Struble	2-1999
5,776,178	Pohndorf et al.	7-1998
5,551,427	Altman	9-1996
5,902,329	Hoffmann et al.	5-1999
5,837,006	Ocel et al.	11-1998
5,447,534	Jammet	9-1995
5,531,780	Vachon	7-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5, 7, 8, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (4886074).

Bisping discloses the claimed invention in figures 1-5 with electrode, 3, guiding mechanism, 8, movement assembly, 5, 9, and 3, with piston, 5, base, 3, knob, 9 or 12, slot, 10 or 11a, and helix, 7, except for the mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Bisping, with a mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant since it was known in the art that heart leads use a mesh screen disposed on the electrode tip to allow fibrous connective tissue to intertwine with

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the screen to firmly secure the electrode and since it was known in the art for heart leads to use a helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, to provide a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

1. A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising:	Bisping shows in figure 1 the distal tip electrode of the cardiac lead at the distal end, 1, of electrode lead, 2.
an electrode tip;	Bisping shows in figure 1 the electrode tip, 3 (e.g. col. 3, line 54).
a mesh screen disposed at a distal end of the electrode tip;	Bisping does not show the mesh screen at a distal end of the electrode tip. Evidence was provided by the examiner to show this notoriously well known element. Specifically Dutcher et al., figures 1-9, or Heil, Jr. et al, figures 1, 2, 5, and 6, element 26 or figure 7, element 118.

<p>a surface at the distal end of the electrode tip;</p>	<p>Bisping shows in figure 1 the surface at the distal end of electrode tip, 3</p>
<p>a helix disposed within said electrode, said helix adapted for travel along a radial axis of the electrode through said surface, the helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating coating including an active ingredient;</p>	<p>Bisping shows in figure 1, the helix, 7, disposed within electrode, 3, that is adapted to travel along a radial axis of the electrode through said surface (e.g. col. 4, lines 1-32, figure 4). Bisping does not show the helix including non-soluble insulating material coated on at least a portion of its surface and the coating including an active ingredient.</p> <p>Evidence was provided by the Examiner to show these notoriously well known limitations. Specifically, Dutcher shows in figure 5 a non-soluble insulating material coating on at least a portion of the helix's surface that conforms to the outer surface of the helix and contains an active ingredient (e.g. element 138, plastic plug with steroid drug, col. 4, lines 57-68). In addition, Dutcher also shows another insulating coating in figure 5, as element 133 that will also contain the active ingredient due to the migration of the drug from element 138.</p>

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	Altman also describes a helix covered with an insoluble coating containing a drug (e.g. col. 14, lines 3-15, col. 14, line 44 to col. 15, line 12, claim 8 of Altman). Struble describes the use of an insulator on a helix (e.g. figures 8A and B), Pohndorf et al describes a drug coating on the helix (e.g. abstract), and Heil, Jr. et al describes a drug coating on the helix (e.g. col. 4, lines 15-67).
a guiding mechanism for directing movement of the fixation device during travel; and	Bisping shows the guiding mechanism as element 8 (e.g. col. 4, line 8).
a movement assembly, said movement assembly for providing movement to said fixation device.	Bisping describes the movement assembly as elements 12, 9, 5, and/or 3 (e.g. col. 3, line 55 to col. 4, line 32).

Claims 1, 2, 3, 7, 8, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (4624265).

Grassi discloses the claimed invention in figure 4 with electrode, 21, guiding mechanism, 20, movement assembly, 14 and 17, seal, 16, base, 17, and piston, 14 between seals 16, and helix, 15, except for the mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant. It would have been obvious to one having ordinary skill in the art at the time the invention was

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made to modify the heart lead as taught by Grassi, with a mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant since it was known in the art that heart leads use a mesh screen disposed on the electrode tip to allow fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it was known in the art for heart leads to use a helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, to provide a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

1. A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising:	Grassi shows in figure 4 the distal tip electrode of the cardiac lead as the distal end of sheath, 6.
an electrode tip;	Grassi shows in figure 4 the electrode tip, 21 (e.g. col. 4, line 14).
a mesh screen disposed at a distal end of the electrode tip;	Grassi does not show the mesh screen at a distal end of the electrode tip. Evidence was provided by the examiner to show this

	notoriously well known element. Specifically Dutcher et al., figures 1-9, or Heil, Jr. et al, figures 1, 2, 5, and 6, element 26 or figure 7, element 118.
a surface at the distal end of the electrode tip;	Grassi shows in figure 4 the surface at the distal end of electrode tip, 21
a helix disposed within said electrode, said helix adapted for travel along a radial axis of the electrode through said surface, the helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating coating including an active ingredient;	Grassi shows in figure 4, the helix, 15, disposed within electrode, 21, that is adapted to travel along a radial axis of the electrode through said surface (e.g. col. 4, lines 17-24, figures 1 and 4). Grassi does not show the helix including non-soluble insulating material coated on at least a portion of its surface and the coating including an active ingredient. Evidence was provided by the Examiner to show these notoriously well known limitations. Specifically, Dutcher shows in figure 5 a non-soluble insulating material coating on at least a portion of the helix's surface that conforms to the outer surface of the helix and contains an active ingredient (e.g. element 138, plastic plug with steroid drug, col. 4, lines 57-68). In

	<p>addition, Dutcher also shows another insulating coating in figure 5, as element 133 that will also contain the active ingredient due to the migration of the drug from element 138. Altman also describes a helix covered with an insoluble coating containing a drug (e.g. col. 14, lines 3-15, col. 14, line 44 to col. 15, line 12, claim 8 of Altman). Struble describes the use of an insulator on a helix (e.g. figures 8A and B), Pohndorf et al describes a drug coating on the helix (e.g. abstract), and Heil, Jr. et al describes a drug coating on the helix (e.g. col. 4, lines 15-67).</p>
<p>a guiding mechanism for directing movement of the fixation device during travel; and</p>	<p>Grassi shows the guiding mechanism as element 20 (e.g. figure 4, col. 4, line 2).</p>
<p>a movement assembly, said movement assembly for providing movement to said fixation device.</p>	<p>Grassi describes the movement assembly as elements 14 and 17 (e.g. figure 4, col. 3, line 63 to col. 4, line 24).</p>

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi.

Grassi discloses the claimed invention except for the knob and slot mating with the knob to form a stop mechanism. It would have been obvious to one having ordinary skill in the art at

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the time the invention was made to modify the heart lead as taught by Grassi, with a knob and slot mating with the knob to form a stop mechanism since it was known in the art that heart leads use a knob and slot mating with the knob to form a stop mechanism to prevent the helix from being retracted further into the lead and causing damage to the lead.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping or Grassi as applied to claim 1 above. The modified Bisping or Grassi discloses the claimed invention with a traveling helix through a mesh screen except for the groove guide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the mesh and helical lead as taught by the modified Bisping or Grassi, with a groove guide since it was known in the art that leads with traveling helixes use a groove guide to guide the helix through the distal end of the lead body/mesh to smoothly guide the helix to exit and enter the lead body.

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(10) Response to Argument

NOTE--The Applicant is not arguing that the Examiner is improperly applying “well known in the art” 103 rejections using a single reference, but that the Bisping or Grassi single reference 103 rejections are not combinable with the other cited prior art evidence, such as Dutcher, Altman, Hoffmann, Heil, etc. This prior art evidence was cited and discussed in several office actions to show the notoriously well known elements discussed in the 103 rejections. In addition, the Applicant in the brief discusses this prior art evidence as if it was combined with Bisping or Grassi.

Discussion of the rejection of claims 1-5, 7, and 8 under 35 USC 103(a) as being unpatentable over Bisping.

The argument that the drug plug, 138, of Dutcher “cannot be properly construed as a coating of non-soluble insulating material. Accordingly, even if combined with Bisping, the combined structure does not read on the claimed: non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient” is not persuasive since the Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. The Applicant has only argued that Dutcher does not have the claimed limitation, but does not state why Dutcher does not have the claimed limitation or rebut the Examiners previous discussion of Dutcher in the office action of 8/4/2006. Specifically, Dutcher shows in figures 5, 8, and 9, the plastic drug plug, 138/238, covering/coating a portion of the outer surface of the helix, wherein the drug plug also contains

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an active ingredient. See col. 4, lines 46-68 or col. 6, lines 32-36. In addition, Dutcher shows the helix also containing another insulative coating, 133 or 233 (e.g. col. 3, line 57), that conforms to an outer surface of the helix and contains an active ingredient from drug plug, 138, due to the migration of the drug from the plug or touching of the plug to insulative coating, 133 or 233.

The argument that Altman is not explicit that the polymer is non-soluble because Altman states there is a biodegradation of the polymer is not persuasive since Altman discloses other embodiments where the polymer is non-soluble. Specifically, Altman states in column 15, lines 5-12 the use of non-soluble polymers as the insulative/non-conductive materials and discusses in column 10, lines 25-30 how a non-soluble insulative coating contains a drug similar to what is disclosed in US patent 5342628.

The argument that Altman's coatings are directed toward "effective elimination of an arrhythmogenic site" in contrast to Bisping which relates to an implantable electrode type lead assembly and therefore it appears the two are generally used for different purposes is not persuasive since both Altman and Bisping are in the same field of endeavor, i.e. fixation helices used to screw into the heart.

The argument that Hoffman does not have a non-soluble coating on a helix is not persuasive since Hoffman was used to show the use of an active ingredient/drug in a non-soluble coating for use on a fixation device (i.e. the tines of Hoffman).

The argument that Appellant believes the office action has provided insufficient motivation to modify the Bisping reference is not persuasive since the Examiner has provided motivation for all the claimed elements as seen in the 103 rejections above. The examiner

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recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In addition, in view of the recent KSR International Co. Vs. Teleflex Inc. Supreme Court Decision, the combination of well known familiar elements, such as the helical lead of Bisping or Grassi, with the mesh and helical insulative coating with active ingredient as set forth in the prior art of Dutcher, Altman, Struble, Heil, Hoffman, etc. would yield the predictable results of providing a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart without causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

The argument in the last full paragraph on page 10 that the office action merely applies hindsight analysis to find obviousness is not persuasive since it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Discussion of the rejection of claims 16-19 under 35 USC 103(a) as being unpatentable over Bisping.

The Applicant's arguments that they cannot find in Bisping the fixation helix including a non-soluble insulating material with active ingredient coated on at least a portion of the helix's outer surface and that the discussion for claim 1 is incorporated herein by reference are not persuasive. Please see the Examiners discussion for claim 1 above (and incorporated herein) as to why the arguments are not persuasive.

Discussion of the rejection of claims 1, 2, 3, 7, and 8 under 35 USC 103(a) as being unpatentable over Grassi.

The Applicant argues that they cannot find in Grassi the fixation helix including a non-soluble insulating material with active ingredient coated on at least a portion of the helix's outer surface and further argues the same position in regards to Dutcher and Altman as discussed in the Applicant's arguments for claim 1 in view of Bisping. Please see the Examiners discussion for claim 1 above (and incorporated herein) as to why the arguments are not persuasive.

Discussion of the rejection of claims 16-19 under 35 USC 103(a) as being unpatentable over Grassi.

The Applicant's arguments that they cannot find in Grassi the fixation helix including a non-soluble insulating material with active ingredient coated on at least a portion of the helix's outer surface and that the discussion for claim 1 is incorporated herein by reference are not persuasive. Please see the Examiners discussion for claim 1 above (and incorporated herein) as to why the arguments are not persuasive.

Discussion of the rejection of claims 4 and 5 under 35 USC 103(a) as being unpatentable over Grassi.

The Applicant's argument that the Office Action has provided insufficient motivation to modify the cited reference of Grassi is not persuasive since the Examiner has provided motivation for all the claimed elements as seen in the 103 rejection above. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In addition, in view of the recent KSR International Co. Vs. Teleflex Inc. Supreme Court Decision, the combination of well known familiar elements, such as the helical lead of Grassi, with the knob and slot mating with the knob to form a stop mechanism as set forth in the cited prior art of Bisping, Ocel, Jammet, etc. would yield the predictable results of preventing the helix from being retracted further into the lead and causing damage to the lead.

Discussion of the rejection of claim 6 under 35 USC 103(a) as being unpatentable over Grassi or Bisping.

The Applicant's argument that the Office Action has provided insufficient motivation to modify the cited reference of Grassi or Bisping is not persuasive since the Examiner has provided motivation for all the claimed elements as seen in the 103 rejection above. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

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suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In addition, in view of the recent *KSR International Co. Vs. Teleflex Inc.* Supreme Court Decision, the combination of well known familiar elements, such as the helical lead of Bisping or Grassi, with a groove guide as set forth in the prior art of Vachon, Ocel, etc. would yield the predictable results of guiding the helix through the distal end of the lead body/mesh to smoothly guide the helix to exit and enter the lead body.

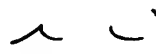
(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

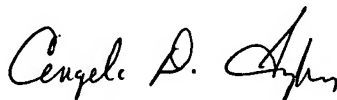
Respectfully submitted,

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